Clinical trial results:
Effect of norepinephrine infusion on hepatic blood flow during goal-directed hemodynamic therapy.

Summary

EudraCT number	2018-004139-66
Trial protocol	BE
Global end of trial date	23 October 2020

Results information

Result version number	v1 (current)
This version publication date	06 July 2024
First version publication date	06 July 2024
Summary attachment (see zip file)	Final Study Report (Finale_Study_Report.pdf)

Trial information

Trial identification

Sponsor protocol code	AGO/2018/006

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UZ Gent
Sponsor organisation address	C. Heymanslaan 10, Gent, Belgium, 9000
Public contact	Hiruz CTU, Ghent University Hospital, +32 93320530, hiruz.ctu@uzgent.be
Scientific contact	Hiruz CTU, Ghent University Hospital, 093320530 93320530, hiruz.ctu@uzgent.be

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	07 August 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 October 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the effect of norepinephrine infusion (NOR) on hepatic blood flow and hepatic vascular pressures during goal-directed hemodynamic therapy.

Protection of trial subjects:

See attachement

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 May 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 28
Worldwide total number of subjects	28
EEA total number of subjects	28

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	10
From 65 to 84 years	18
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

See attachement

Pre-assignment

Screening details:

See Attachement

Period 1

Period 1 title	Overal Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

Not relevant

Arms

Are arms mutually exclusive?	Yes
Arm title	Group S

Arm description:

See attachement

Arm type	group S
Investigational medicinal product name	Norepinephrine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

See attachement

Arm title	Group NS

Arm description:

See attachement

Arm type	Group NS
Investigational medicinal product name	Norepinephrine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

See attachement

Number of subjects in period 1	Group S	Group NS
Started	20	8
Completed	20	8

Baseline characteristics

End points

End points reporting groups

Reporting group title	Group S
Reporting group description:	
See attachement	
Reporting group title	Group NS
Reporting group description:	
See attachement	

Primary: Primary

End point title	Primary[1]
End point description:	
End point type	Primary
End point timeframe:	
See attachement	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: See attachement

End point values	Group S	Group NS		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	8		
Units: Subjects	20	8		

Statistical analyses

No statistical analyses for this end point

Secondary: Secondary

End point title	Secondary
End point description:	
End point type	Secondary
End point timeframe:	
See attachement	

End point values	Group S	Group NS		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	8		
Units: Subjects	20	8		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
During the study	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

Frequency threshold for reporting non-serious adverse events: 0 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: See attachement

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported